

SCHEDULES

SCHEDULE 2

Section 29.

SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Consultation with appropriate committee or Commission

- 1 Except as provided by paragraph 11 of this Schedule, where the licensing authority propose, in the exercise of their powers under section 28 of this Act.—
 - (a) to suspend, revoke or vary a product licence on the grounds specified in paragraph (a) or paragraph (c) of subsection (3) of that section, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products of a description to which the licence relates, or
 - (b) to suspend, revoke or vary a product licence on any of the grounds specified in paragraph (g) or paragraph (h) of that subsection,the licensing authority shall not suspend, revoke or vary the licence except after consultation with the appropriate committee or, if for the time being there is no such committee, with the Commission.
- 2 Where the appropriate committee or the Commission are consulted under the preceding paragraph, and on any such grounds as are mentioned in that paragraph they have reason to think that they may have to advise the licensing authority that the product licence ought to be suspended, revoked or varied, the committee or Commission shall notify the holder of the licence accordingly, and, before giving any such advice to the licensing authority, shall afford to him an opportunity of appearing before and being heard by them, or of making representations in writing to them with respect to those grounds.
- 3 Where the holder of the licence has availed himself of the opportunity of being heard under paragraph 2 of this Schedule, or after considering any representations made by him under that paragraph, the appropriate committee or the Commission, as the case may be, shall report to the licensing authority their findings and advice and the reasons for their advice, and the licensing authority shall take that report into account in making their decision.
- 4 Whether the holder of the licence has been heard or has made representations under paragraph 2 of this Schedule or not, if the appropriate committee or the Commission advise the licensing authority that the licence ought on any such grounds as are mentioned in paragraph 1 of this Schedule to be suspended or revoked, or to be varied so as to contain provisions specified in their advice, the licensing authority shall serve notice on the holder of the licence stating the advice so given to the authority and the reasons stated by the appropriate committee or the Commission for giving that advice.
- 5 If, within the time allowed after the service of a notice under paragraph 4 of this Schedule, in a case where the holder of the licence has not been heard by, or made representations to, the Commission under paragraph 2 of this Schedule, the holder

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of the licence gives notice to the licensing authority of his desire to be heard with respect to the advice given to the authority, or makes representations in writing to the licensing authority with respect to that advice, then, before determining the matter.—

- (a) if the holder of the licence has given notice of his desire to be heard, the licensing authority shall arrange for him to have an opportunity of appearing before and being heard by the Commission, or
- (b) if he has made representations in writing, the licensing authority shall refer those representations to the Commission,

and, where the holder of the licence has availed himself of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report to the licensing authority their findings and advice and the reasons for their advice, and the licensing authority shall take that report into account in making their decision.

6 If the licensing authority—

- (a) propose to determine the matter in a way which differs from the advice of the Commission under paragraph 3 or paragraph 5 of this Schedule, or
- (b) where there has been no hearing before, and no representations have been made or referred to, the Commission, propose to determine the matter in a way which differs from the advice of the appropriate committee under paragraph 3 of this Schedule, or
- (c) in the absence of any such advice as is mentioned in either of the preceding sub-paragraphs, propose to determine the matter in a way which differs from the advice given by the appropriate committee or the Commission, or
- (d) propose to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,

the licensing authority shall notify the holder of the licence accordingly, and, before determining the matter, shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to that proposal.

7 Any notification given to the holder of the licence under paragraph 6 of this Schedule—

- (a) in a case falling within sub-paragraph (a) or sub-paragraph (b) of that paragraph, shall state the advice of the Commission or the appropriate committee and the reasons stated by the Commission or the committee for giving that advice, or
- (b) in a case falling within sub-paragraph (c) of that paragraph, shall state the advice given by the appropriate committee or the Commission and the reasons stated by the committee or the Commission for giving that advice,

and in a case falling within sub-paragraph (d) of that paragraph (whether it also falls within any of the other sub-paragraphs of that paragraph or not) the notification shall include a statement of the proposals of the licensing authority and of the reasons for them.

Notification of proposals to holder of licence in other cases

8 Except as provided by paragraph 11 of this Schedule, where the licensing authority propose, in the exercise of the powers conferred by section 28 of this Act.—

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- (a) to suspend, revoke or vary a licence under Part II of this Act, other than a product licence, or
- (b) to suspend, revoke or vary a product licence where no notice of that proposal, or of any advice, or grounds for giving advice, which led to that proposal, has been given to the holder of the licence under paragraph 2, paragraph 4 or paragraph 6 of this Schedule,

the licensing authority shall serve on the holder of the licence a notice stating their proposals and the reasons for them and the date (not being earlier than twenty-eight days from the date of service of the notice) on which it is proposed that the suspension, revocation or variation should take effect.

- 9 If, before the date specified in a notice under paragraph 8 of this Schedule, the holder of the licence gives notice to the licensing authority of his desire to be heard under this paragraph, or makes representations in writing to the licensing authority with respect to their proposals, then, before determining the matter, the licensing authority shall afford to him an opportunity of appearing before, and being heard by a person appointed for the purpose by the licensing authority, or shall take those representations into account, as the case may be.

Procedure in case of urgency

- 10 The following provisions of this Schedule shall have effect where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under Part II of this Act with immediate effect.
- 11 In the circumstances specified in paragraph 10 of this Schedule, the licensing authority may, notwithstanding anything in paragraphs 1 to 9 of this Schedule, suspend the licence with immediate effect for a period not exceeding three months.
- 12 If the licence is a product licence, the licensing authority shall report the suspension forthwith to the appropriate committee or, if for the time being there is no such committee, to the Commission.
- 13 If, after the suspension has taken effect, it appears to the licensing authority, or (in the case of a product licence) they are advised by the appropriate committee or by the Commission, that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority (subject to the next following paragraph) shall proceed in accordance with such of the provisions of paragraphs 1 to 9 of this Schedule as are applicable in the circumstances.
- 14 Where, in the circumstances specified in paragraph 13 of this Schedule, the licensing authority proceed as mentioned in that paragraph, and any proceedings under paragraphs 1 to 9 of this Schedule relating to a further suspension of the licence have not been finally disposed of before the end of the period for which the licence was suspended under paragraph 11 of this Schedule, or for which it has been further suspended under this paragraph, as the case may be, then, if it appears to the licensing authority to be necessary in the interests of safety to do so, the licensing authority may further suspend the licence for a period which (in the case of each such further suspension) shall not exceed three months.
- 15 The provisions of section 27(7) of this Act shall, with the necessary modifications, have effect for the purpose of determining the date on which, for the purposes of paragraph 14 of this Schedule, any proceedings are to be finally disposed of.

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Provisions as to hearings

- 16 Subsection (7) of section 21 of this Act shall have effect in relation to a person appointed by the licensing authority under paragraph 6 or paragraph 9 of this Schedule as it has effect in relation to a person appointed under subsection (5) of that section, as if in the said subsection (7) any reference to the applicant were a reference to the holder of the licence.